



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/858,318	05/15/2001	Gregory J. Kellogg	674182-2004	3092
20999 7590 01/24/2007 FROMMER LAWRENCE & HAUG 745 FIFTH AVENUE- 10TH FL. NEW YORK, NY 10151			EXAMINER LEVKOVICH, NATALIA A	
			ART UNIT	PAPER NUMBER
			1743	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		01/24/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	09/858,318	KELLOGG ET AL.	
	Examiner	Art Unit	
	Natalia Levkovich	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 November 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7,9-23 and 32-42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7,9-23 and 32-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. Applicant's amendments and remarks filed 11/03/2006 have been acknowledged by the Examiner.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-7, 9-23 and 32-42 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 1 recites manifolds comprising a micro-channel 'positioned radically across the surface of the platform'. Examiner assumes that the intended term was 'radially', as can also be concluded from the discussion in the Remarks. Upon further reviewing the

Art Unit: 1743

original specification, the Examiner found no support for this limitation. On the contrary, Figures 4B and 10 show manifolds 409, 210 arranged circumferentially.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-7, 9-23 and 32-42 are rejected under 35 U.S.C. 112, second paragraph, as being unclear for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, the limitation, 'mixing microchannel ... having a length sufficient to mix the sample solution and the reagent solutions to a homogenous mixture', is unclear and indefinite. The mixing process depends on many factors. Two channels of the same length, but having, for example, different shapes (and, therefore, different hydrodynamic conditions), can (in one case) allow, or (in another case) not allow a proper mixing.

Claim Rejections - 35 USC § 102

7. The 35 U.S.C. 102(b) rejection of claims 1-7, 9-23 and 32-42 as being anticipated by European publication 0 608 006 to Abaxis, Inc., is withdrawn.

Claim Rejections - 35 USC § 103

8. Claims 1-7, 9-23 and 32-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Abaxis.

Art Unit: 1743

As was discussed in the 06/05/2006 Office Action, Abaxis teaches analytical device comprising microsystem platforms which utilize centripetal forces to move fluids throughout the device. As shown in Figure 1, the device comprises a microfluidic structure which includes a plurality of reservoirs, such as a blood / sample application reservoir, a metering chamber (which separates the "bulk" fluid into an exact amount and an excess amount), an overflow chamber, a reagent chamber and a detection chamber. All of the chambers are fluidly connected to one another via channels (including a mixing chamber / channel). See the appropriate paragraphs of the 06/05/2006 Office Action.

Abaxis does not teach a 'multiplicity' of microfluidic circuits each having the above mentioned structure. However, it would have been clearly within the ordinary skill of an artisan at the time the invention was made to have arranged a plurality of microfluidic circuits on the platform of the modified apparatus of Abaxis, in order to provide simultaneous processing of multiple samples.

Double Patenting

9. Claims 1-7, 9-24 and 32-56 remain rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, 5-20 and 29-37 of U.S. Patent No. 6,582,662 to Kellogg et al in view of US Patent 6,063,589 to Kellogg et al. See the appropriate paragraphs of the 06/05/2006 Office Action.

Art Unit: 1743

10. Claims 1-7,9-23 remain provisionally rejected under the judicially created doctrine of obviousness- type double patenting as being unpatentable over claims 1-22 of co-pending Application No. 10/746,821 in view of US Patent 6,063,589 to Kellogg et al. See the appropriate paragraphs of the 06/05/2006 Office Action.

11. Claims 37 and 38 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-2 of U.S. Patent No. 6,709,869 to Mian et al in view of US Patent 6,063,589 to Kellogg et al. See the appropriate paragraphs of the 06/05/2006 Office Action.

Response to Arguments

12. Applicant's arguments filed with the request for continued examination have been fully considered but they are not persuasive and moot in view of new grounds of rejection.

Applicant argues that the double patenting rejections are overcome. Examiner notes that these rejections are maintained and cannot be held in abeyance until corresponding terminal disclaimers are filed.


Conclusion

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natalia Levkovich whose telephone number is 571-272-2462. The examiner can normally be reached on Mon-Fri, 8 a.m.-4p.m..

Art Unit: 1743

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Jill Warden
Supervisory Patent Examiner
Technology Center 1700